

Substitute for form 1448A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/780,294
				Filing Date	February 17, 2004
				First Named Inventor	Dow, Steven W.
				Art Unit	1633
				Examiner Name	SAJJADI, Fereydoun Ghotb
Sheet	1	of	1	Attorney Docket Number	021819-000200US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
FS ↓	AA	US-6,893,086	02/17/2004	Dow, et al.	
	AB	US-6,589,940	07/08/2003	Raz, et al.	
	AC	US-6,627,615 B1	09/30/2003	Debs, et al.	
	AD	US-2003/0022854	01/30/2003	Dow, et al.	
	AE	US-			
	AF	US-			
	AG	US-			
	AH	US-			
	AI	US-			
	AJ	US-			
	AK	US-			
	AL	US-			
	AM	US-			
	AN	US-			
	AO	US-			
	AP	US-			
AQ	US-				
AR	US-				

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
FS	AS	PCT	WO99/66879	A2	12/29/1999	National Jewish Medical Research Center		<input type="checkbox"/>
	AT							<input type="checkbox"/>
	AU							<input type="checkbox"/>
	AV							<input type="checkbox"/>
	AW							<input type="checkbox"/>

Examiner Signature	/Fereydoun Sajjadi/	Date Considered	12/15/2006
--------------------	---------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



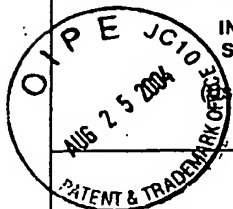
Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Complete If Known</b>	
		Application Number	10/780,294
		Filing Date	February 17, 2004
		First Named Inventor	Dow, Steven W.
		Art Unit	1632
		Examiner Name	Anne Marie Falk
Sheet 1 of 1	Attorney Docket Number	021819-000200US	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
FS	BC	CORNELIE, S., et al. "Methylated cpG-Containing Plasmid Activates the Immune System", <i>Scandinavian Journal of Immunology</i> (2004) 59:143-151	
FS	BD	SASAKI, Shin, et al. "Adjuvant formulations and delivery systems for DNA vaccines", <i>Methods</i> (2003) 31:243-254	
	BE		
	BF		
	BG		
	BH		
	BI		
	BJ		
	BK		
	BL		
	BM		

Examiner Signature	/Fereydoun Sajjadi/	Date Considered	12/15/2006
--------------------	---------------------	-----------------	------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (10/01) (Substitute for form 1449A/PTO)	ATTY. DOCKET NO. 2879-54-4 Client/Matter No. 86715.0005.000	APPLICATION NO. 10/780,294
	FIRST NAMED INVENTOR Steven W. Dow	
	FILING DATE February 17, 2004	ART UNIT 1632

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

Sheet 1 of 5

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document No. No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
FS	1	US-6,121,247	09/19/2000	Huang et al.	
	2	US-6,224,901 B1	05/01/2001	Li et al.	
	3	US-5,830,878	11/03/1998	Gorman et al.	
	4	US-5,827,703	10/27/1998	Debs et al.	
	5	US-5,593,972	01/14/1997	Weiner et al.	
	6	US-5,641,662	06/24/1997	Debs et al.	
	7	US-5,643,578	07/01/1997	Robinson et al.	
	8	US-5,676,954	10/14/1997	Brigham	
	9	US-5,679,647	10/21/1997	Carson et al.	
	10	US-5,693,622	12/02/1997	Wolff et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Doc entry code - No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
						YES	NO
FS	11	WO 94/04196	03/03/1994	Imperial Cancer Research Technology Limited		X	
FS	12	WO 93/25673	12/23/1993	The Regents of the University of California		X	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published
FS	13	EYAL RAZ, DENNIS A. CARSON, et al. "Cationic Lipids Inhibit Intradermal Genetic Vaccination," Vaccines 94, Cold Spring Harbor Laboratory Press (1994) pp. 71-75.
	14	INDER M. VERMA and NIKUNJ SOMIA, "Gene Therapy - promises, problems and prospects," Nature, Volume 389 (1997) pp. 239-242.
	15	STUART H. ORKIN, M.D. and ARNO G. MOTULSKY, M.D., "Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy," Dec. 7, 1995, pp.1-41.

EXAMINER SIGNATURE /Fereydoun Sajjadi/	DATE CONSIDERED 12/15/2006
---	-------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>PTO/SB/08A (10/01)</b> (Substitute for form 1449/APTO)		<b>ATTY. DOCKET NO. 2879-54-4</b> Client/Matter No. 86715.0002		<b>APPLICATION NO.</b> 10/780,294	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)  Sheet 2 of 5		<b>FIRST NAMED INVENTOR</b> Steven W. Dow			
		<b>FILING DATE</b> February 17, 2004		<b>ART UNIT</b> 1632	

U.S. PATENT DOCUMENTS					
Examine r Initials	Cite No.	Document No. No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	16	5,703,055	12/30/1997	Felgner et al.	
	17	5,703,057	12/30/1997	Johnston et al.	
	18	5,830,878	11/03/1998	Gorman et al.	
	19	5,589,466	12/31/1996	Felgner et al.	
	20	5,580,859	12/03/1996	Felgner et al.	
	21	5,399,348	03/21/1995	Anderson et al.	
	22	5,013,556	05/07/1991	Woodle et al.	
	23	5,043,164	08/27/1991	Huang et al.	

FOREIGN PATENT DOCUMENTS							
Examine r Initials	Cite No.	Foreign Patent Doc cntry code - No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
						YES	NO
FS	24	EP 0 819 758 A2	01/21/1998	James Archibald Mlxson		X	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examine r Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published
	25	XIANG GAO, "Cationic Lipid-Based Gene Delivery: An Update," pp. 99-112.
	26	DAVID M. RODMAN, ELIZABETH G. NABEL, "Delivery of Genes Through the Lung Circulation," pp. 181-191.
	27	BRUCE D. FREIMARK, et al., "Cationic Lipids Enhance Cytokine and Cell Influx Levels in the Lung Following Administration of Plasmid: Cationic Lipid Complexes," J. Immunology, 1998, pp. 4581-4586.
	28	TOSHIKO YAMAMOTO, et al., "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity," Microbial. Immunol., 38(10), pp. 831-836, 1994.
	29	ZUHAIR K. BALLAS, et al., "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA," Journal of Immunology, pp. 1840-1845, 1996.

<b>EXAMINER SIGNATURE</b> <div style="text-align: center;">/Fereydoun Sajjadi/</div>	<b>DATE CONSIDERED</b> <div style="text-align: center;">12/15/2006</div>
---	---

<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
--

<b>PTO/SB/08A (10/01)</b> (Substitute for form 1449A/PTO)		<b>ATTY. DOCKET NO. 2879-54-4</b> Client/Matter No. 86715.0002		<b>APPLICATION NO.</b> 10/780,294	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)		<b>FIRST NAMED INVENTOR</b> Steven W. Dow			
Sheet 3 of 5		<b>FILING DATE</b> February 17, 2004		<b>ART UNIT</b> 1632	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document No. No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<div style="font-size: 2em;">↓</div>	30	5,686,101	11/11/1997	Tagawa et al.	
	31	5,817,856	10/6/1998	Tirosh et al.	
	32	5,705,187	01/06/1998	Unger	
	33	5,820,873	10/13/1998	Choi et al.	
	34	4,957,735	09/18/1990	Huang	

FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Foreign Patent Doc cntry code - No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
						YES	NO

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published
<div style="font-size: 2em;">↓</div>	35	ARTHUR M. KRIEG, "Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA," Trends in Microbiology, Vol. 4 No. 2 February 1996 pp.1-5.
	36	DAVID S. PISETSKY, "The Immunologic Properties of DNA," J. Immunology, 1996, pp. 441-423.
	37	YUKIO SATO, et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization," Science, Vol. 273, 19 July 1996 pp. 352-354.
	38	KATRYN J. STACEY, et al., "Macrophages Ingest and Are Activated by Bacterial DNA," J. Immunology, 1996 pp. 2116-2122
	39	SIQUAN SUN, et al. "Dual Function of Drosophila Cells as APCs for Native CD8 <sup>+</sup> TCells: Implications for Tumor Immunotherapy," Immunity, June 1996 Vol. 4, pp 555-564.
	40	YONG LIU, et al. "Factors influencing the efficiency of cationic liposome-mediated intravenous gene delivery," Nature Biotechnology, Volume 15, February 1997, pp.167-173.
	41	WOLFGANG W. LEITNER, et al., "DNA and RNA-based vaccines: principles, progress and prospects," Vaccine 18, 2000, pp. 765-777.
	42	LESLIE A. LESOON-WOOD, et al., "Systemic Gene Therapy with p53 Reduces Growth and Metastases of a Malignant Human Breast Cancer in Nude Mice," Human Gene Therapy 6:395-405, April 1995.
	43	T. OKAMOTO, et al., Proceedings of the American Assoc. for Cancer Research, Vol. 38, March 1997, abstract # 78.
	44	J. NAJTOH, et al., Proceedings of the American Assoc. for Cancer Research, Vol. 39, March 1998, abstract # 2421.

<b>EXAMINER SIGNATURE</b> /Fereydoun Sajjadi/	<b>DATE CONSIDERED</b> 12/15/2006
---	-----------------------------------

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>PTO/SB/08A (10/01)</b> (Substitute for form 1449A/PTO)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)  Sheet 4 of 5	<b>ATTY. DOCKET NO. 2879-54-4</b> Client/Matter No. 86715.0002	<b>APPLICATION NO.</b> 10/780,294
	<b>FIRST NAMED INVENTOR</b> Steven W. Dow	
	<b>FILING DATE</b> February 17, 2004	<b>ART UNIT</b> 1632

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document No. No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Doc cntry code - No. - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
						YES	NO

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published
FS	45	XIU-MIN LI, et al. "Mucosal IFN- $\gamma$ Gene Transfer Inhibits Pulmonary Allergic Responses in Mice," J. Immunology, 1996, pp. 3216-3219.
	46	JOHN W. MCLEAN, et al. "Organ-specific endothelial cell uptake of cationic liposome-DNA complexes in mice," The American Physiological Society, pp. H387-H404.
	47	DAVID S. PISETSKY, "Immune Activation by Bacterial DNA: A New Genetic Code," Immunity, Vol. 5., pp. 303-310, October 1996.
	48	MARK ROMAN, et al. "Immunostimulatory DNA sequences function as T helper - 1- promoting adjuvants," Nature Medicine, Aug. 1997, Volume 3, Number 8, pp. 849-854.
	49	STEVEN A. ROSENBERG, et al. "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-dose Recombinant Interleukin 2," J. Exp. Med Vol 161, pp.1169-1188, May 1985.
	50	RONALD K. SCHEULE, et al. "Basis of Pulmonary Toxicity Associated with Cationic Lipid-Mediated Gene Transfer to the Mammalian Lung," Human Gene Therapy, vol. 8, pp. 689-707, April 10, 1997.
	51	NANCY SMYTH TEMPLETON, et al. "Improved DNA: Liposome complexes for increased systemic delivery and gene expression," Nature Biotechnology Volume 15, July 1997 pp. 647-652.
	52	GREGORY GREGORIADIS, et al. "Liposome-mediated DNA vaccination," FEBS Letters 402 (1997) pp. 107-110.
	53	RODNEY J.Y. HO, et al. "Interactions of Target-sensitive Immunoliposomes with Herpes Simplex Virus," Journal of Biological Chemistry, Vol. 262, No. 29, (1987) pp.13979-13984.
✓	54	RODNEY J.Y. HO, et al. "Target-sensitive Immunoliposomes as an Efficient Drug Carrier for Antiviral Activity," Journal of Biological Chemistry, Vol. 262, No. 29 (1987) pp. 13973-13978.

<b>EXAMINER SIGNATURE</b> /Fereydoun Sajjadi/	<b>DATE CONSIDERED</b> 12/15/2006
--	--------------------------------------

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>PTO/SB/08A (10/01)</b> (Substitute for form 1449A/PTO)		<b>ATTY. DOCKET NO. 2879-54-4</b> Client/Matter No. 86715.0002		<b>APPLICATION NO.</b> 10/780,294	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)  Sheet 5 of 5		<b>FIRST NAMED INVENTOR</b> Steven W. Dow			
		<b>FILING DATE</b> February 17, 2004		<b>ART UNIT</b> 1632	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document No. – Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
FS	55	5,935,568	08/10/1999	Dow et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Doc entry code – No. – Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Doc	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	TRANSLATION
						YES    NO

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published
FS	56	RODNEY J.Y. HO, et al., "Target-Sensitive Immunoliposomes: Preparation and Characterization," Biochemistry Vol. 25, (1986) pp. 5500-5506.
	57	T.M. ALLEN, et al., "Large unilamellar liposomes with low uptake into the reticuloendothelial system," FEBS Letters, Vol. 223, No. 1, (1987), pp. 42-46.
	58	ALEXANDER L. KLIBANOV, "Amphiphilic polyethyleneglycols effectively prolong the circulation time of liposomes," FEBS Letters, Vol. 268, No. 1, (1990), pp. 235-237.
	59	MARTIN C. WOODLE, et al., "Sterically stabilized liposomes," Biochimica et Biophysica Acta, 1113 (1992) pp. 171-199.
	60	Hiroaki Hemmi, et al., 2002, Nature Immunology, 3(2): 196-200.

<b>EXAMINER SIGNATURE</b> <div style="text-align: center;">/Fereydoun Sajjadi/</div>	<b>DATE CONSIDERED</b> <div style="text-align: center;">12/15/2006</div>
---	---

<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
--